APPENDIX O

Selected EPA Guidance Documents for Lead

Appendix O

Selected EPA Guidance Documents for Lead

This appendix contains three EPA guidance documents for conducting lead human health risk assessments. These documents are:

1. Revised Interim Soil Lead Guidance for CERCLA Sites and RCRA Corrective Action Facilities, written by the Office of Solid Waste and Emergency Response in August 1994 (OSWERdir9355.4-12.pdf).
2. Clarification to the 1994 Revised Interim Soil Lead Guidance for CERCLA Sites and RCRA Corrective Action Facilities, written by the Office of Solid Waste and Emergency Response in August 1998 (OSWER98-9200.4-27P.pdf).
3. IEUBK Model Bioavailability Variable, written by the Technical Review Workgroup for Lead in October 1999 (IEUBK Model Bioavailability.pdf).

IEUBK Model Bioavailability Variable

INTRODUCTION

Performance of the Integrated Exposure Uptake Biokinetic Model for Lead (Pb) in Children (IEUBK) is a function of site-specific parameter input values. A site-specific determination of soil-borne lead bioavailability is, therefore, advantageous for improving predictiveness of the model. This short sheet discusses issues to consider and applicable methods for determining a site-specific bioavailability value for soil-borne lead.

The current default estimate for the bioavailability of soil/dust in the IEUBK model is 30 percent as an absolute value. This absorption fraction is partitioned into a non-saturable component (6 percent) and a saturable component (24 percent). Investigators (Casteel *et al.*, 1997; Henningsen *et al.*, 1998) have observed variable bioavailability across different soil/lead matrices, although the majority of samples are generally consistent with the IEUBK default value. Soil particle size (for soils sieved to <250 µm or 60-mesh), mineralogy, and lead speciation are among the factors that influence bioavailability (Steele *et al.*, 1990).

In Vitro techniques, such as the physiologically-based extraction test (PBET - Ruby *et al.*, 1996), have been developed as a means of capturing the impact of the soil/lead matrix on bioavailability. However, physico-chemical characteristics of the soil/lead matrix are not the sole determinants of the highly complex biological process of gastrointestinal absorption. In effect, solubility and bioavailability are not interchangeable terms. Until such time that fully validated *in vitro* techniques become generally accepted, the recommended approach to demonstrating site-specific bioavailability will need to be supported by an appropriate animal bioassay.

This short sheet reaffirms the provisions of the 1995 *Administrative Reform for Lead* that requires review of data that may set a precedent. Bioavailability data (other than from published studies using the juvenile swine model) that are intended for use in an EPA risk assessment using the IEUBK should be sent for review by the Office of Emergency and Remedial Response. This review not only promotes better science but also promotes sharing of information so that all EPA Regions can benefit from new information/analyses.

DEFINITIONS

As indicated in the Guidance Manual for the IEUBK Model, **bioavailability** refers to "the fraction of the total amount of material in contact with a body portal-of-entry (lung, gut, skin) that enters the blood." Bioavailability is also described as absolute or relative (USEPA, 1994). **Absolute bioavailability** is the amount of a substance entering the blood via a particular route of exposure (*e.g.*, gastrointestinal) divided by the total amount administered (*e.g.*, soil lead ingested). **Relative bioavailability** is indexed by measuring the bioavailability of a particular substance relative to the bioavailability of a standardized reference material, such as soluble lead acetate.

It should be noted that the bioavailability input parameter in the IEUBK model is an absolute value, but it may be experimentally determined by relative means, provided that the absolute bioavailability of the "standardized reference material" is known. For the IEUBK model, soluble lead in water and food is estimated to have 50 percent absolute bioavailability. The model presumes that the relative bioavailability of lead in soil is 60 percent, thus producing an absolute bioavailability for soil lead of 30 percent (*i.e.*, 60% x 50% = 30%). It is acknowledged that this value has significant variability and uncertainty, but it is the estimate under which the IEUBK model was validated with comprehensive blood lead study results.

"**Bioaccessability**" is a term used in describing an event that relates to the absorption process. It generally refers to the fraction of administered substance that becomes solubilized in the gastrointestinal fluid. For the most part, solubility is a prerequisite of absorption, although small amounts of lead in particulate or suspended/emulsified form may be absorbed by pinocytosis. Moreover, it is not simply the **fraction** dissolved that determines bioavailability, but also the **rate** of dissolution, which has physiological and geochemical influences. In and of itself, bioaccessability is not a direct measure of the movement of a substance across a biological membrane (*i.e.*, absorption or bioavailability). The relationship of bioaccessability to bioavailability is ancillary and the former need not be known in order to measure the latter.

However, bioaccessability (*i.e.*, solubility) may serve as a surrogate for bioavailability if certain conditions are met (see *Methods and Issues to Consider when Determining Site-Specific Bioavailability of Soil-Borne Lead*).

As previously mentioned, lead absorption is believed to occur by both **active** and **passive** mechanisms. Although the precise subcellular processes involved in lead absorption are not entirely known, active/passive absorption processes (depending on dose) can impart a curvilinear shape to a graph of dose *vs* blood lead concentration. The potential impact of active and passive absorption processes on the determination of relative bioavailability is discussed in a latter section (*Methods and Issues to Consider when Determining Site-Specific Bioavailability of Soil-Borne Lead*).

WHEN TO CONSIDER ADJUSTMENTS IN BIOAVAILABILITY

As stated in the *Introduction*, the bioavailability of soil-borne lead is influenced by numerous characteristics of the soil-lead matrix. Particle size has been demonstrated to effect soil-lead bioavailability (Steele *et al.*, 1990). Although a strong quantitative relationship between particle size and bioavailability has not been established, an understanding of particle size distribution in a soil-lead source may provide qualitative information on the potential bioavailability of the source material. Perhaps more importantly, available data (Henningsen *et al.*, 1998) indicate that lead speciation can have a significant effect on bioavailability.

Currently, *in vivo* bioassays are the only way to quantitatively measure and adjust default bioavailability to fit site soils. However, validation studies are in progress which show promise for *in vitro* tests which may be correlated to the *in vivo* results. Such a test would have obvious and much needed advantages of speed, affordability, simplicity, and higher throughput. Until such tests are sufficiently validated with *in vivo* data, the use of *in vitro* bioaccessibility results are deemed by EPA to represent insufficient evidence for quantitative adjustment of bioavailability. The reason for this position is that small changes in *in vitro* assays, such as pH, time, temperature, volume, other solutes, and agitation regimes, can have relatively large impacts on results of lead solubility. Until validation is confirmed, the use of a simpler, faster, and cheaper lab benchtop test will not, in and of itself, be judged an adequate surrogate for measuring bioavailability.

Results of tests by EPA using animal models have shown a general pattern of relative bioavailability for certain lead salts. While lead speciation is not the sole factor influencing bioavailability, these patterns can, nonetheless, be used to compare a site's form of soil lead to explore differences in bioavailability relative to the defaults. If the lead speciation profile suggests a bioavailability estimate substantially different from the IEUBK model default, then the costs and benefits of performing supporting animal tests for now, and possibly of *in vitro* tests after validation, can be considered for quantitative measures of bioavailability, and adjustments for a specific site. Furthermore, qualitative estimates of relative bioavailability can be made in the uncertainty section of a risk assessment. General patterns of relative bioavailability determined by EPA Region 8 studies of 20 soil lead samples (Henningsen *et al.*, 1998), compared to the default soil relative bioavailability of 60 percent, are shown as groups below:

Potentially Lower Bioavailability (RBA < 25%)	**Intermediate Bioavailability (RBA = 25% to 75%)**	**Potentially Higher Bioavailability (RBA > 75%)**
Galena (PbS) Anglesite ($PbSO_4$) Pb (M) Oxides Pb Fe (M) Sulfates Native Pb	Pb Oxide Pb Fe (M) Oxides Pb Phosphate Slags	Cerrusite ($PbCO_3$) Pb Mn (M) Oxides

Pb = lead, S = sulfur, M = metals, Fe = iron, Mn = manganese

Results of well-conducted blood lead studies can infer relatively low bioavailability of lead in soil. Such findings would not support a quantitative adjustment of bioavailability, but could assist in identifying soils for further study and/or support a qualitative adjustment in the risk characterization section of a risk assessment.

METHODS AND ISSUES TO CONSIDER WHEN DETERMINING SITE-SPECIFIC BIOAVAILABILITY OF SOIL-BORNE LEAD

Ethics aside, in a hypothetical setting the ideal method for making a bioavailability adjustment for soil-borne lead in the IEUBK model would be to dose a large group of young children with soil-borne lead and compare the area-under-the-concentration/time curve (AUC) with the AUC of the same or similar group which received an equal lead dose by intravenous administration. This is the conventional pharmacological and toxicological method for measuring *absolute* bioavailability. Realistically, issues of ethics, cost, and implementation are important determinants of study design. Consequently, an alternate approach is to measure soil-lead bioavailability *relative* to a "standardized reference material" (see *Definitions* section).

Determination of relative bioavailability needs to consider the experimental evidence suggesting that gastrointestinal lead absorption follows first-order saturation kinetics. An example is presented to illustrate that relative bioavailability, as estimated from experimental studies, can depend strongly on the response levels at which comparisons are made. The approach used to estimate relative bioavailability is to compare doses of lead (in different forms) that, upon ingestion by an experimental animal, produce equal levels of biological response (in this example, blood lead concentrations). The curves in the Figure illustrate relationships that may be fit to experimental data on the relationship between the ingested dose of lead and resulting blood lead measures. The two curves are of the Michaelis-Menten form (Equation 1) with vmax = 30, km = 1 in the soluble lead relationship and vmax = 10, km = 0.4 for the soil lead relationship.

$$\text{Absorption rate} = \frac{vmax \times dose}{km + dose} \qquad \textbf{Equation 1}$$

where

vmax = maximum rate at which an enzyme can function.

km = concentration of substrate that produces 50% maximum velocity of the enzyme.

This example is hypothetical, in that the curves shown are for purposes of illustration and are not intended to represent a specific data set. However, similar models, using Michaelis-Menten form equations, have been presented to EPA as models of bioavailability data from rodent studies conducted with soils from Superfund sites.

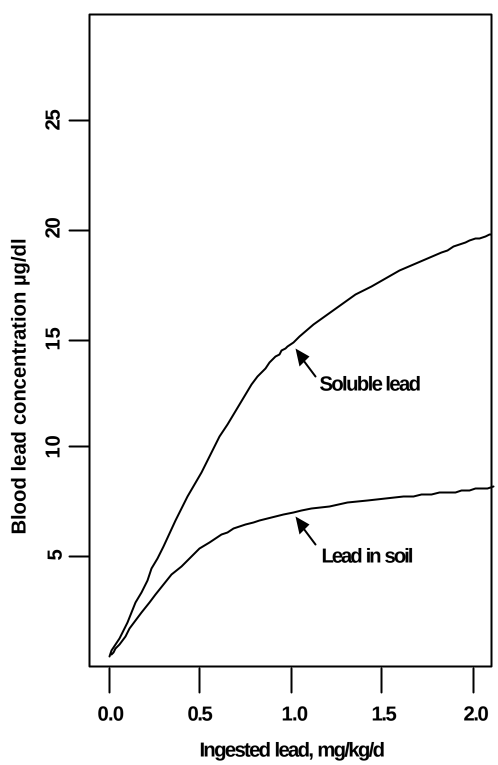
To estimate relative bioavailability in this example, a reference blood lead concentration is selected (5 µg/dL). The dose levels of soluble lead and lead in soil, respectively, at which this blood concentration is produced are then estimated. As illustrated in the Figure, a dose of 0.2 mg/kg/d of soluble lead is associated with a blood lead level of 5 µg/dL, while a dose of lead in soil of 0.4 mg/kg/d is required to achieve this same level. The relative bioavailability is estimated to be 0.5 or 50 percent based on the ratio of these doses (0.2/0.4).

However, in this example, where the soluble lead graph and the soil lead graph show different curvatures (specifically resulting from the different km values in the example), the estimated relative bioavailability depends on blood lead level at which the comparisons are made (see figure below).

Note that at low doses the relative bioavailability of the two materials is similar, while at high doses the relative bioavailability of lead in soil is estimated to be low

Hypothetical response curve for lead uptake study

Example showing different stages of response for soil lead and soluble lead



compared with soluble lead. A variety of different mechanistic factors may affect the bioavailability of lead administered at high doses. In experimental studies of bioavailability, substantial amounts of soil may be administered to the experimental animals, and the presence of these high quantities of soil in the diet may affect the bioavailability of lead. Such effects may be due to alterations to the chemical environment of the GI tract. For example, the presence of substantial quantities of soil may provide additional binding sites for lead, reducing the likelihood that any lead which becomes solubilized will remain in solution and be absorbed.

Blood lead concentration for calculating relative bioavailability (µg/dL)	**Dose of soluble lead to achieve this concentration (mg/kg/day)**	**Dose of soil lead to achieve this concentration (mg/kg/day)**	**Relative bioavailability**
1.00	0.03	0.04	0.78
2.00	0.07	0.10	0.71
3.00	0.11	0.17	0.65
4.00	0.15	0.27	0.58
5.00	0.20	0.40	0.50
6.00	0.25	0.60	0.42
7.00	0.30	0.93	0.33
8.00	0.36	1.60	0.23

Due to the potential for high doses of either soil or lead itself to affect (reduce) absorption, experimental bioavailability studies need to be performed at low enough doses to provide a reasonable comparison with the quantities of soil and lead that humans are likely to ingest. Where experimental limitations necessitate that the quantities of soil or lead administered substantially exceed the expected human doses (on a body weight basis), it should be recognized that an extrapolation to lower doses may be appropriate. This extrapolation step may take the form of an explicit mathematical treatment of the data (and as such would need to address the uncertainty in the predictions at low dose) or it may involve a more qualitative demonstration that under the particular experimental conditions utilized, the estimated bioavailability is not highly sensitive to the lead dosage used for comparison.

SITE SOIL HOMOGENEITY FOR SAMPLE COLLECTION AND PREPARATION

Soil samples that are tested for *in vivo* bioavailability or *in vitro* bioaccessibility should be obtained from areas that are reasonably similar (*i.e.,* similar geophysical and chemical properties of lead in soil). The top 2 inches of surface soil from residential yards should be representatively sampled and composited for testing. It is critical to sieve soil samples to <250 µm (60 mesh) to more closely represent the size of soil particles that would be expected to adhere to children's hands. An extremely useful tool for geophysical-chemical characterization of lead in soil is the electron microprobe (Medlin, 1997). Soil samples which are characterized or tested for bioavailability must retain their integrity, including chain of custody documentation, and proper mixing that provides a uniform subsample without physically degrading the soil particles.

APPROPRIATE ANIMAL MODEL

Because of the difficulties in gathering data on oral absorption of lead in children, there is no validated ***absolute model*** for experimental uses in measuring bioavailability. Each candidate animal model is expected to respond uniquely to absolute lead absorption (*i.e.,* oral uptake *vs.* intravenous dosing), compared to children, because of differences in physiology, diet, behavior, and development. However, it is possible to use a similar mammalian gastrointestinal system to measure ***relative*** absorption in comparison to the uptake of a soluble lead reference material (*e.g.,* lead acetate). This is the concept underlying the juvenile swine model (Weis *et al.,*1994) which has further advantages of permitting sequential blood sampling and responding to doses similar to those experienced by children. Further details on the appropriate design aspects of such studies can be obtained from Weis *et al.,* 1994; Casteel *et al.,* 1997; and Henningsen *et al.,* 1998.

Previous rodent studies have had limitations due to:

(1) rapid development which often resulted in testing of sexually mature animals which may have lost some of their active transport uptake of lead;

(2) inability to produce AUC blood lead results *vs.* time, due to rodents' small size which precludes repeat blood sampling;

(3) necessity to dose rodents with exceptionally high doses of soil lead to generate elevations in blood lead. Such high doses would fall into the saturation portion of the dose-response curve for other animals and probably for children, making accurate extrapolations of bioavailability difficult, if not impossible;

(4) delivery of soil lead to rodents in food *vs.* in a small amount of vehicle, due to practical matters of dosing by oral gavage. This prevents assessment of bioavailability in a partially fasted state and results in a highly variable dose (mg/kg-d body

weight) over the term of exposure due to high growth rates in rodents; and

(5) other confounders unique to rodents. Other animal models also have had their limitations in estimating quantitative bioavailability of lead in soil, and so the juvenile swine model used by EPA appears to be the most useful model.

Currently, the juvenile swine model (Weis *et al.*, 1994) design offers the strongest method to measure site-specific bioavailability, since it attempts to mimic childhood absorption and doses of lead in soil relative to soluble lead acetate. Critical to this or any future or alternative study is the need to test a representative soil lead sample which best reflects the geophysical and chemical nature of the lead in residential yards. Composite sampling of relatively homogeneous types of lead in surficial soil can produce an acceptable test sample. In the near future, promising *in vitro* models may be validated that correlates well with the *in vivo* swine model results. When approved by EPA, these validated models will have utility for screening soil and dust samples for relative bioavailability and can provide quantitative measures of bioaccessibility that can reasonably predict bioavailability of lead in soils with an acceptable amount of uncertainty.

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EPA/540/F-98/030
PB98-963244

OSWER Directive # 9200.4-27P

MEMORANDUM

SUBJECT: Clarification to the 1994 Revised Interim Soil Lead Guidance for CERCLA Sites and RCRA Corrective Action Facilities

FROM: Timothy Fields, Jr.
Acting Assistant Administrator

TO: Regional Administrators I-X

PURPOSE

This directive clarifies the existing 1994 Revised Interim Soil Lead Guidance for CERCLA Sites and RCRA Corrective Action Facilities, OSWER Directive 9355.4-12. Specifically, this directive clarifies OSWER's policy on (1) using EPA's Science Advisory Board (SAB) reviewed Integrated Exposure Uptake Biokinetic Model (IEUBK) and blood lead studies, (2) determining the geographic area to use in evaluating human exposure to lead contamination ("exposure units"), (3) addressing multimedia lead contamination and (4) determining appropriate response actions at lead sites. The purpose for clarifying the existing 1994 directive is to promote national consistency in decision-making at CERCLA and RCRA lead sites across the country.

BACKGROUND

OSWER Directive 9355.4-12, issued on July 14, 1994 established OSWER's current approach to addressing lead in soil at CERCLA and RCRA sites. The existing directive established a streamlined approach for determining protective levels for lead in soil at CERCLA sites and RCRA facilities as follows:

- It recommends a 400 ppm screening level for lead in soil at residential properties;
- It describes how to develop site-specific preliminary remediation goals (PRGs) at CERCLA sites and media cleanup standards at RCRA Corrective Action facilities for residential land use; and,
- It describes a strategy for management of lead contamination at CERCLA sites and RCRA Corrective Action facilities that have multiple sources of lead.

The existing interim directive provides direction regarding risk assessment and risk management approaches for addressing soil lead contaminated sites. The OSWER directive states that, " ... implementation of this guidance is expected to provide more consistent decisions across the country ..." However, since that directive was released, OSWER determined that clarification of the guidance is needed. Key areas being clarified by issuance of this directive include: (1) using the IEUBK model and blood lead studies, (2) determining exposure units to be considered in evaluating risk and developing risk management strategies, (3) addressing multimedia lead contamination and (4) determining appropriate response actions at residential lead sites. The existing directive provides the following guidance on these areas:

1. The OSWER directive recommends using the Integrated Exposure Uptake Biokinetic (IEUBK) Model for Lead in Children (Pub. # 9285.7-15-1, PB93-963510) for setting site-specific residential preliminary risk-based remediation goals (PRGs) at CERCLA sites and media cleanup standards (MCSs) at RCRA corrective actions Facilities. The directive states that the IEUBK model is the best tool currently available for predicting the potential blood lead levels of children exposed to lead in the environment. OSWER's directive also recommends the evaluation of blood lead data, where available, and states that well-conducted blood lead studies provide useful information to site managers. The directive however recommends that "... blood lead data not be used <u>alone</u> to assess risk from lead exposure or to develop soil lead cleanup levels."

2. The directive describes OSWER's risk reduction goal as "...generally, OSWER will attempt to limit exposure to soil lead levels such that a typical (or hypothetical) child or group of similarly exposed children would have an estimated risk of no more than 5% of exceeding a 10 ug/dl blood lead level." The directive also states that "... EPA recommends that a soil lead concentration be determined so that a typical child or group of children exposed to lead at this level would have an estimated risk of no more than 5% of exceeding a blood lead of 10 ug/dl." OSWER generally defines an exposure unit as a geographic area where exposures occur to the receptor of concern during the time of interest and believes that for a child or group of similarly exposed children, this is typically the individual residence and other areas where routine exposures are occurring.

3. The directive recommends that risk managers assess the contribution of multiple environmental sources of lead to overall lead exposure (e.g., consideration of the importance of soil lead levels relative to lead from drinking water, paint, and household dust) which promotes development of risk reduction strategies that address all sources that contribute significantly to exposure.

4. The OSWER directive states that the IEUBK model is not the only factor to be considered in establishing lead cleanup goals. Rather, the IEUBK model is the primary risk assessment tool available for evaluating lead risk and the results of the model are used to guide selection of appropriate risk management strategies for each site.

Since the OSWER directive was issued in 1994, there has been a trend toward a more consistent approach to managing risk at residential lead sites, however, OSWER was interested in identifying areas requiring additional clarification to facilitate more effective implementation of the directive. As a first step in the process, meetings were held with various EPA Regions, States and local governments to discuss how the directive has been implemented nationally at lead sites since 1994. By participating in these meetings and by reviewing the decisions that are being made across the country, OSWER believed that clarification of certain aspects of the 1994 directive would be useful.

All of the documents and guidance referenced in this directive are available through the National Technical Information Service (NTIS) at 703-605-6000 or could be downloaded electronically from: http//epa.gov/superfund/oerr/ini_prod/lead/prods.htm.

OBJECTIVE

At lead contaminated residential sites, OSWER seeks assurance that the health of the most susceptible population (children and women of child bearing age) is protected and promotes a program that proactively assesses and addresses risk. OSWER believes that predictive tools should be used to evaluate the risk of lead exposure, and that cleanup actions should be designed to address both current and potential future risk.

While health studies, surveys, and monitoring can be valuable in identifying current exposures and promoting improved public health, they are not definitive tools in evaluating potential risk from exposure to environmental contaminants. In the case of lead exposure, blood lead monitoring programs can be of critical importance in identifying individuals experiencing potential negative health outcomes and directing education and intervention resources to address those risks. However, CERCLA §121(b) requires EPA to select cleanup approaches that are protective of human health and the environment and that utilize permanent solutions to the maximum extent practicable. To comply with the requirements set forth in CERCLA § 121(b), OSWER will generally require selection of cleanup programs that are proactive in mitigating risk and that do not simply rely on biological monitoring programs to determine if an exposure has already occurred.

To meet these objectives, OSWER will seek actions that limit exposure to soil lead levels such that a typical child or group of similarly exposed children would have an estimated risk of no more than 5% of exceeding a 10 µg/dl blood lead level. If lead is predicted to pose a risk to the susceptible population, OSWER recommends that actions be taken to significantly minimize or eliminate this exposure to lead.

The principles laid out in the **four attached fact sheets** (Appendix) support OSWER’s goals by encouraging appropriate assessment and response actions at CERCLA and RCRA lead sites across the country.

This clarification directive emphasizes the following key messages regarding the four areas and encourages the users of this directive, be they EPA Regions, States, or other stakeholders, to adopt these principles in assessing and managing CERCLA and RCRA lead sites across the country. The critical elements of the attached papers are as follows:

I. Using Blood Lead Studies and IEUBK Model at Lead Sites:

OSWER emphasizes the use of the IEUBK Model for estimating risks for childhood lead exposure from a number of sources, such as soils, dust, air, water, and other sources to predict blood lead levels in children 6 months to 84 (7 years) months old. The 1994 directive also recommended evaluation of available blood lead data and stated that data from a well-conducted blood lead study of children could provide useful information to site managers. In summary, OSWER's clarification policy on the appropriate use of the IEUBK and blood lead studies is that:

- OSWER recommends that the IEUBK model be used as the primary tool to generate risk-based soil cleanup levels at lead sites for current or future residential land use. If Regions propose an alternative method for generating cleanup levels, they are required to submit their approach to the national Lead Sites Consultation Group (LSCG)[1] for review and comment ;

- Response actions can be taken using IEUBK predictions alone; blood lead studies are not required; and

- Blood lead studies and surveys are useful tools at lead sites and can be used to identify key site-specific exposure pathways and to direct health professionals to individuals needing immediate assistance in minimizing lead exposure; however, OSWER recommends that blood lead studies not be used for establishing long-term remedial or non-time-critical removal cleanup levels at lead sites.

II. Determining Exposure and Remediation Units at Lead Sites

OSWER recommends that cleanup levels at lead sites be designed to reduce risk to a typical or individual child receiving exposures at the residence to meet Agency guidelines (*i.e.*, no greaterthan a 5% chance of exceeding a 10 ug/dl blood-lead level for a full-time child resident). Therefore, it is recommended that risk assessments conducted at lead-contaminated residential sites use the individual residence as the primary exposure unit of concern. This does not mean that a risk assessment should be conducted for every yard, rather that the soil lead contamination

[1]The Lead Sites Consultation Group (LSCG) is comprised of senior management representatives from the Waste Management Divisions in all 10 EPA regions along with senior representatives from the Office of Emergency and Remedial Response in EPA headquarters. The LSCG is supported by EPA's Technical Review Workgroup (TRW) for lead and the national Lead Sites Workgroup (LSW). The TRW consists of key scientific experts in lead risk assessment from various EPA Regions, labs and headquarters. The LSW is comprised of senior Regional Project Managers from various Regions and key representatives from headquarters who are experienced in addressing lead threats at Superfund sites.

data from yards and other residential media (for example, interior dust and drinking water) should be input into the IEUBK model to provide a preliminary remediation goal (PRG) for the residential setting. When applicable, potential exposure to accessible site-related lead sources outside the residential setting should also be evaluated to understand how these other potential exposures contribute to the overall risk to children, and to suggest appropriate cleanup measures for those areas.

III. Addressing Multimedia Contamination at Lead Sites

EPA generally has limited legal authority to use Superfund to address exposure from **interior lead-based paint**. As a policy matter, OSWER recommends that such exposures not be addressed through actual abatement activities. However, EPA Regions should promote addressing interior paint risks through actions by others (e.g., potentially responsible parties (PRPs), other government programs, etc.) as a component of an overall site management strategy. Because of other competing demands on the Superfund Trust Fund**,** OSWER recommends that EPA Regions avoid using the Superfund Trust Fund for removing **exterior lead-based paint** and soil contaminated from lead-based paint. Superfund dollars *may* however be used in limited circumstances to remediate exterior lead-based paint in order to protect the overall site remedy (i.e., to avoid re-contamination of soils that have been remediated) but generally only after determining that other funding sources are unavailable. As with interior lead-based paint abatement, EPA Regions should promote remediation of exterior lead-based paint by others, such as PRPs, local governments or individual homeowners.

IV. Determining Appropriate Response Actions at Lead Sites

In selecting site management strategies, it is OSWER's preference to seek early risk reduction with a combination of engineering controls (actions which permanently remove or treat contaminants, or create reliable barriers to mitigate the risk of exposure) and non-engineering response actions. All potential lead sources should be identified in site assessment activities. Non-engineering response actions, such as education and health intervention programs, should be considered an integral part of early risk reduction efforts because of their potential to provide immediate health benefits. In addition, engineering controls should be implemented early at sites presenting the greatest risk to children and other susceptible subpopulations.

As a given project progresses, OSWER's goal should be to reduce the reliance on education and intervention programs to mitigate risk. The goal should be cleanup strategies that move away from reliance on long-term changes in community behavior to be protective since behavioral changes may be difficult to maintain over time. The actual remedy selected at each CERCLA site must be determined by application of the National Oil and Hazardous Substances Pollution Contingency Plan (NCP) (55 FR 8666- 8865, March 8, 1990) remedy selection criteria to site-specific circumstances. This approach also recognizes the NCP preference for permanent remedies and emphasizes selection of engineering over non-engineering remedies for long-term response actions.

This directive clarifies OSWER's policy on four key issue areas addressed in the 1994 OSWER soil lead directive in order to promote a nationally consistent decision-making process for assessing and managing risks associated with lead contaminated sites across the country. The policy presented in these specific issue areas supersedes all existing OSWER policy and directives on these subjects. No other aspects of the existing 1994 directive are affected.

IMPLEMENTATION

The principles laid out in this directive (which includes the four attached factsheets) are meant to apply to all residential lead sites currently being evaluated through the CERCLA Remedial Investigation/Feasibility Study process and all future CERCLA Sites and RCRA Corrective Action Facilities contaminated with lead. The Regions will be required to submit their rationale for deviating from the policies laid out in this directive to the Lead Sites Consultation Group. This directive does not apply to previous remedy selection decisions.

Attachments

cc: Waste Management Policy Managers (Regions I-X)
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NOTICE: This document provides guidance to EPA staff. The document does not, however, substitute for EPA's statutes or regulations, nor is it a regulation itself. Thus it cannot impose legally-binding requirements on EPA, states, or the regulated community, and may not apply to a particular situation based upon the circumstances. EPA may change this guidance in the future, as appropriate.

Factsheet: Using the IEUBK Model and Blood Lead Studies at Residential Lead Sites

Question: What is OSWER's policy on using the IEUBK model and blood-lead studies in conducting risk assessments and setting cleanup standards at residential lead contamination sites?

Answer: OSWER's policy on using the IEUBK model and blood-lead studies in conducting risk assessment and setting cleanup standards is as follows:

A. Use of the IEUBK Model:

1. The IEUBK model is a good predictor of potential long-term blood-lead levels for children in residential settings. OSWER recommends that the IEUBK model be used as the primary tool to generate risk-based soil cleanup levels at lead sites for current or future residential land use. If Regions propose an alternative method for generating cleanup levels, they are required to submit their approach to the National Lead Sites Consultation Group (LSCG) for review and comment.

2. Blood-lead distributions predicted by the IEUBK model illustrate a plausible range of variability in children's physiology, behavior, and household conditions.

3. Response actions can be taken, and remedial goals developed, using IEUBK predictions alone.

B. Use of Blood-Lead Studies/Data:

1. Blood-lead studies, surveys, and monitoring are useful tools at lead sites and can be used to help identify key site-specific exposure pathways and direct health professionals to individuals needing immediate assistance in minimizing lead exposure.

2. The utility of blood lead testing results and studies depends on how representative the information is of the population being evaluated, the design of the data collection, and the quality of the laboratory analysis. To this end, OSWER recommends that EPA Regions consult with ATSDR or CDC to assess or design studies according to their intended use.

3. Many blood-lead screening, monitoring, or testing programs differ from blood lead studies in that they do not attempt to identify risk factors for childhood exposure to lead sources. Although these programs may be extremely beneficial in identifying children with elevated blood lead levels and identifying candidates for referral to medical professionals for evaluation, they may not provide an accurate representation of community-wide exposure.

4. Well-designed blood lead studies may be used to identify site specific factors and pathways to be considered in applying the IEUBK model at residential lead sites. However, OSWER recommends that blood-lead studies not be used to determine future long-term risk where exposure conditions are expected to change over time; rather, they should be considered a snapshot of ongoing exposure under a specific set of circumstances (including community awareness and education) at a specific time. Long-term studies may be helpful in understanding exposure trends within a community and evaluating the effectiveness of cleanup strategies over time.

C. <u>IEUBK and Blood-Lead Studies/Data:</u>

1. Blood-lead data and IEUBK model predictions are expected to show a general concordance for most sites. However, some deviations between measured and predicted levels are expected. On some occasions, declines in blood-lead levels have been observed in association with lead exposure-reduction and health education. However, long-term cleanup goals should be protective in the absence of changes in community behavior as there is little evidence of the sustained effectiveness of these education/intervention programs over long periods of time.

2. Where actual blood-lead data varies significantly from IEUBK Model predictions, the model parameters should not automatically be changed. In such a case, the issue should be raised to the Lead Technical Review Workgroup (TRW) to further identify the source of those differences. Site work need not be put on hold while the issue is being reviewed by the TRW; the site manager should review other elements of the lead directive and the "Removal Actions at Lead Sites" guidance to determine appropriate interim actions to be taken at the site.

The Regions will be required to submit their rationale for deviating from the policies laid out in this factsheet to the Lead Sites Consultation Group.

Factsheet: Determining Exposure and Remediation Units at Residential Lead Sites

Question: How does OSWER define an exposure unit, and subsequently apply this definition in conducting risk assessment and risk management activities at residential lead sites?

Answer: OSWER recognizes that defining and characterizing exposure unit(s) for a site is critically important in undertaking risk assessment activities and in designing protective cleanup strategies. An **exposure unit** is defined as a geographic area where exposures occur to the receptor of concern during the time of interest and that for a child, or group of similarly exposed children, this is typically the individual residence and other areas where chronic or ongoing exposures are occurring.

Various approaches to characterizing and managing risks by exposure units have been examined by OSWER. OSWER recognizes that lead ingestion can also cause adverse health effects in adults and fetuses but believes that by adequately limiting lead exposures to young children at residential sites, these other receptors will generally be likewise protected from adverse health impacts.

EPA's goal is to protect human health and the environment under current and future exposure scenarios. At lead sites, OSWER wants to assure that children's health is protected and promotes a program that proactively assesses risks rather than relying on biological monitoring to determine if an exposure has already occurred. OSWER emphasizes actions be taken at lead sites that will minimize or eliminate exposure of children to environmental lead contamination.

To achieve the above stated goal, OSWER recommends characterizing **exposure units as exposure potential at the individual residence as the primary unit of concern for evaluating potential risk at lead contaminated residential sites**. This recognizes that there are children whose domain and activities occur principally within the confines of a particular residential property. For determining exposure potential (and ultimately developing protective cleanup levels) at the individual home, OSWER recommends the scenario to be evaluated (through use of the IEUBK Model) would be a young child in full-time residence. This approach helps achieve OSWER's recommended health protection goal that an individual child or group of similarly exposed children would have <5% chance of exceeding a blood-lead concentration of 10 ug/dl. In designing community wide cleanup strategies, it is essential that non-residential areas (e.g., parks, day care facilities, playgrounds, etc.), where lead exposure may occur, also be characterized with respect to their contribution to soil-lead exposure, and appropriate cleanup actions implemented.

OSWER recommends that risk management decisions for response to residential lead contamination sites focus on reducing risk at residences, but also recommends that response strategies be developed for other site locations (exposure units) where children receive exposure. Flexibility in determining appropriate response actions that provide protection at the individual residence should be considered in context of the NCP remedy selection criteria. The lead exposure issues are complex and OSWER recommends that EPA Regions try to communicate clearly the risk characterization and risk management decisions to the site residents. Affected communities must clearly understand the context of risk management decisions, how these decisions affect the health of their children, and how cleanup actions will influence the future growth and development of the community.

The Regions will be required to submit their rationale for deviating from the policies laid out in this factsheet to the Lead Sites Consultation Group.

Factsheet: Addressing Multimedia Contamination at Residential Lead Sites

Question: What is OSWER's policy on addressing multimedia contamination at residential lead sites?

Answer: OSWER recognizes that several sources of lead-contamination, including soil, ground water, airborne particulates, lead plumbing, interior dust, and interior and exterior lead-based paint may be present at Superfund sites where children are at risk or have documented lead exposure. These lead sources may contribute to elevated blood-lead levels and may need to be evaluated in determining risks and cleanup actions at residential lead sites. However, there are limitations on the Agency's statutory authority under CERCLA to abate some of these sources, such as indoor lead-based paint and lead plumbing because CERCLA responses may be taken only to releases or threatened releases into the environment (CERCLA §104 (a)(3) and (4)).

When EPA's resources, or authority to respond or to expend monies under Superfund is limited, OSWER recommends that EPA Regions identify and coordinate to the greatest extent possible with other authorities and funding sources (e.g., other federal agencies and state or local programs). EPA Regions should coordinate with these other authorities to design a comprehensive, cost-effective response strategy that addresses as many sources of lead as practicable. These strategies should include actions to respond to lead-based paint, interior dust, and lead plumbing, as well as ground water sources and lead-contaminated soil.

Although OSWER will encourage that EPA Regions fully cooperate in the development of a comprehensive site management strategy, OSWER realizes that complete active cleanup of these other sources may be difficult to complete due to limited funding available to other authorities. Since complete cleanups of these sources is not guaranteed, and at most sites may be unlikely, OSWER recommends that the soil cleanup levels not be compromised. In other words, the soil cleanup levels should be calculated with the IEUBK model using existing pre-response action site specific data. This is due to the fact that soil cleanup levels at residential lead sites are generally established to protect individuals, from excess exposures to soils, and house dust attributable to those soils, and are not attributable to exposure to other sources such as interior lead paint which should be managed on a residence specific basis. Remediation of non-soil lead sources to mitigate overall lead exposure at individual residences should therefore not be used to modify sitewide soil lead cleanup levels.

The recommendations provided below represent OSWER's policy on addressing lead-contaminated media and/or sources for which EPA has limited or no authority to remediate.

Interior Paint: EPA has limited legal authority to use Superfund to address exposure from interior lead-based paint. As a policy matter, OSWER recommends that such exposures not be addressed through actual abatement activities. However, EPA Regions should promote addressing interior paint risks through actions by others, such as HUD, local governments, or individual home owners as a component of an overall site management strategy. Any activities to clean up interior lead-based paint by PRPs or other parties should not result in an increase of the risk-based soil cleanup levels.

Exterior Paint: Because of other competing demands on the Superfund Trust Fund, OSWER recommends that EPA Regions avoid using the Superfund Trust Fund for removing exterior lead-based paint and soil contaminated from lead-based paint. Superfund dollars *may* be used to respond to exterior lead-based paint for protecting the overall site remedy (i.e., to prevent re-contamination of soils that have been remediated) but only after determining that other funding sources are unavailable. Where other sources of funding are not available, EPA may utilize the CERCLA monies to remediate exterior lead-based paint on homes/buildings, around which soil contaminated by other sources has been cleaned up to prevent recontamination of the soil. The Superfund should not be used to remediate exterior lead-based paint where no soil cleanup has occurred. As with interior lead-based paint abatement, EPA Regions should promote remediation of exterior lead-based paint by others, such as PRPs, local governments or individual homeowners. Cleanup activities of exterior paint conducted by PRPs or other parties should not result in an increase of the risk-based soil cleanup levels.

Interior Dust: Lead contaminated interior dust can be derived from several sources, including interior paint, home owner hobbies, exterior soil, and other exterior sources. In many cases, it may be difficult to differentiate the source(s) for the lead contamination in the dust. In general, EPA Regions should refrain from using the Superfund Trust Fund to remediate interior dust. Because of the multi-source aspects of interior dust contamination, potential for recontamination, and the need for a continuing effort to manage interior dust exposure, OSWER recommends the use of an aggressive health education program to address interior dust exposure. Such programs, administered through the local health department (or other local agency), should be implemented in conjunction with actions to control the dust source. At a minimum, the program should include blood-lead monitoring, and personal hygiene and good housekeeping education for the residents. OSWER believes that EPA Regions can also support the program by providing HEPA vacuums to the health agency for use in thoroughly cleaning home interiors.

Lead Plumbing: Generally CERCLA does not provide for legal authority to respond to risks posed by lead plumbing within residential dwellings. It should be noted that the water purveyor is responsible for providing clean water to the residences. As with interior dust, OSWER recommends that EPA Regions coordinate with local agencies to establish a health education program to inform residents of the hazards associated with lead plumbing and how to protect themselves by regularly flushing, or preferably, replacing lead pipes. Soil cleanup levels should not be adjusted to account for possible remediation of lead plumbing.

Factsheet: Determining Appropriate Response Actions at Residential Lead Sites

Question: What is OSWER's position on the appropriate use of engineering and non-engineering response actions in developing risk management strategies for lead sites?

Answer: One goal emphasized in the recent third round of Superfund Reforms is for EPA to take a consistent approach in selecting and implementing both long- and short-term response actions at lead sites in all regions. One obstacle to achieving this consistency has been differing degrees of reliance on non-engineering response actions in reducing risk.

Site management strategies at lead sites typically include a range of response actions. Alternatives range from engineering controls that permanently remove or treat the contaminant source to non-engineering response actions, such as educational programs and land use restrictions. This continuum represents the range of response options available to risk managers. This position paper clarifies the relationship between engineering and non-engineering response actions in developing site management strategies.

In selecting site management strategies, OSWER's policy will be to seek early risk reduction with a combination of engineering controls (actions which permanently remove or treat contaminants, or which create reliable barriers to mitigate the risk of exposure) and non-engineering response actions. All potential lead sources should be identified in site assessment activities. Non-engineering response actions, such as education and health intervention programs, should be considered an integral part of early risk reduction efforts due to their potential to provide immediate health benefits.[2] In addition, engineering controls should be implemented early at sites presenting the greatest risk to children and other susceptible subpopulations. Community concerns should receive a high priority in site decision-making; local support is vital to the success of health intervention and education programs.

As the project progresses, OSWER's goal should be to reduce reliance on education and intervention programs to mitigate risk. The goal should be cleanup strategies that move away from reliance on long-term changes in community behavior to be protective; behavioral changes

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[2]The actual effectiveness of health intervention and educational programs in reducing risk continues to be a subject of discussion. Anecdotal information suggests that such programs can provide short-term benefits in some populations. Rigorous statistical studies demonstrating the benefits of educational programs in preventing lead exposure are lacking. It is generally recognized that not all segments of the population will be influenced by such programs, and that long-term benefits are less certain. Local support for such programs is critical. The active (and long-term) participation of local and state public health agencies is needed in implementing institutional controls, including health intervention and education programs; without local implementation of such programs their success is uncertain. Additional research on the effectiveness of these programs is critical to consideration of their use in future cleanups.

may be difficult to maintain over time. The actual remedy selected at each site must be determined by application of the NCP remedy selection criteria to site-specific circumstances. However, this approach recognizes the NCP preference for permanent remedies and emphasizes the use of engineering controls for long-term response actions. This approach also recognizes that well-designed health intervention and education programs, when combined with deed restrictions and/or other institutional controls, may be appropriate for reducing future exposure potential and may supplement engineering controls.

In instances where Regions believe that the use of engineering controls is impracticable, and education, health intervention, or institutional controls are proposed as the sole remedy, Regions will be required to consult with the LSCG.

UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

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OFFICE OF
SOLID WASTE AND EMERGENCY RESPONSE

OSWER Directive # 9355.4-12

MEMORANDUM

SUBJECT: Revised Interim Soil Lead Guidance for CERCLA Sites and RCRA Corrective Action Facilities

FROM: Elliott P. Laws
Assistant Administrator

Elliott P. Laws

TO: Regional Administrators I-X

PURPOSE

As part of the Superfund Administrative Improvements Initiative, this interim directive establishes a streamlined approach for determining protective levels for lead in soil at CERCLA sites and RCRA facilities that are subject to corrective action under RCRA section 3004 (u) or 3008 (h) as follows:

- It recommends screening levels for lead in soil for residential land use 400 (ppm);[1]
- It describes how to develop site-specific preliminary remediation goals (PRGs) at CERCLA sites and media cleanup standards (MCSs) at RCRA Corrective Action facilities for residential land use; and,
- It describes a plan for soil lead cleanup at CERCLA sites and RCRA Corrective Action Facilities that have multiple sources of lead.

This interim directive replaces all previous directives on soil lead cleanup for CERCLA and RCRA programs (see the Background section, 1989-1991).

KEY MESSAGES

Screening levels are not cleanup goals. Rather, these screening levels may be used as a tool to determine which sites or portions of sites do not require further study and to encourage voluntary cleanup. Screening levels are defined as a level of contamination above which there may be enough concern to warrant site-specific study of risks. Levels of contamination above the screening level would NOT automatically require a removal action, nor designate a site as "contaminated."

The residential screening level for lead described in this directive has been calculated with the Agency's new Integrated Exposure Uptake Biokinetic Model (IEUBK) model (Pub. # 9285.7-15-2, PB93-963511), using default parameters. As outlined in the Guidance Manual for the IEUBK Model for Lead in Children (Pub. #

[1]The residential screening level is the same concept as the action level proposed in the RCRA Corrective Action Subpart S rule (July 27, 1990, 55 *Federal Register* 30798).

9285.7-15-1, PB93-963510, February 1994), this model was developed to: recognize the multimedia nature of lead exposure; incorporate important absorption and pharmacokinetic information; and allow the risk manager to consider the potential distributions of exposure and risk likely to occur at a site (the model goes beyond providing a single point estimate output). For these reasons, this approach is judged to be superior to the more common method for assessing risks of non-cancer health effects which utilizes the reference dose (RfD) methodology. Both the Guidance Manual and the model are available to Superfund staff through the Superfund Document Center (703-603-8917) and to the public through the National Technical Information Service (703-487-4650).

Residential preliminary remediation goals (PRGs) for CERCLA remediations and media cleanup standards (MCSs) for RCRA corrective actions can be developed using the IEUBK model on a site-specific basis, where site data support modification of model default parameters. At some Superfund sites, using the IEUBK model with site-specific soil and dust characteristics, PRGs of more than twice the screening level have been identified. However, it is important to note that the model alone does not determine the cleanup levels required at a site. After considering other factors such as costs of remedial options, reliability of institutional controls, technical feasibility, and/or community acceptance, still higher cleanup levels may be selected.

The implementation of this guidance is expected to provide for more consistent decisions across the country and improve the use of site-specific information for RCRA and CERCLA sites contaminated with lead. The implementation of this guidance will aid in determining when evaluation with the IEUBK model is appropriate in assessing the likelihood that environmental lead poses a threat to the public. Use of the IEUBK model in the context of this guidance will allow risk managers to assess the contribution of different environmental sources of lead to overall blood lead levels (e.g., consideration of the importance of soil lead levels relative to lead from drinking water, paint and household dust). It offers a flexible approach to considering risk reduction options (referred to as the "bubble" concept) that allows for remediation of lead sources that contribute significantly to elevated blood lead. This guidance encourages the risk manager to select, on a site-specific basis, the most appropriate combination of remedial measures needed to address site-specific lead exposure threats. These remedial measures may range widely from intervention to abatement. However, RCRA and CERCLA have very limited authority to address interior exposures from interior paint. For detailed discussion of the decision logic for addressing lead-contaminated sites, see the Implementation section and Appendix A.

Relationship to lead paint guidance. In addition, this interim directive clarifies the relationship between guidance on Superfund and RCRA Corrective Action cleanups, and EPA's guidance on lead-based paint hazards (discussed further in Appendix C). The paint hazard guidance will be issued to provide information until the Agency issues regulations identifying lead-based paint hazards as directed by Section 403 of the Toxic Substances Control Act (TSCA)[2]. Lead-based paint hazards are those lead levels and conditions of paint, and residential soil and dust that would result in adverse health effects.

The two guidance documents have different purposes and are intended to serve very different audiences. As a result the approaches taken differ to some degree. The lead-based paint hazard guidance is intended for use by any person who may be involved in addressing residential lead exposures (from paint, dust or soil). It thus relates to a potentially huge number of sites, and serves a very broad potential audience, including private property owners or residents in addition to federal or state regulators. Much residential lead abatement may take place outside any governmental program, and may not involve extensive site-specific study.

This OSWER guidance, on the other hand, deals with a much smaller number of sites, being addressed under close federal regulatory scrutiny, at which extensive site characterization will have been performed before cleanup decisions are made. Thus, the RCRA and CERCLA programs will often have the benefit of much site-specific exposure information. This guidance is intended for use by the relatively small number of agency officials who oversee and direct these cleanups.

Both the TSCA Section 403 and OSWER programs use a flexible, tiered approach. The OSWER guidance sets a residential screening level at 400 ppm. As noted above, this is not intended to be a "cleanup level" for

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[2]Title IV of TSCA (including section 403) was added by the Residential Lead-Based Paint Hazard Reduction Act of 1992 (Title X of the Housing and Community Development Act of 1992).

CERCLA and RCRA facilities, but only to serve as an indicator that further study is appropriate. The Section 403 guidance indicates that physical exposure-reduction activities may be appropriate at 400 ppm, depending upon site-specific conditions such as use patterns, populations at risk and other factors. Although worded somewhat differently, the guidances are intended to be similar in effect. For neither guidance is 400 ppm to automatically be considered a "cleanup level"; instead, it indicates a need for considering further action, but not necessarily for taking action. Neither is meant to indicate that cleanup is necessarily appropriate at 400 ppm. The greater emphasis in this OSWER guidance on determining the scope of further study reflects the fact that both CERCLA and RCRA cleanups proceed in stages with detailed site characterization preceding response actions in every case.

Above the 400 ppm level, the Section 403 guidance identifies ranges over which various types of responses are appropriate, commensurate with the level of potential risk reduction, and cost incurred to achieve such risk reduction. For example, in the range of 400 to 5000 ppm, limited interim controls are recommended depending, as noted above, on conditions at the site, while above 5000 ppm, soil abatement is recommended. This OSWER guidance does not include comparable numbers above 400 ppm; instead, as discussed above, it recommends the site-specific use of the IEUBK model to set PRGs and MCSs, when necessary. The remedy selection process specified in the National Contingency Plan (NCP) should then be used to decide what type of action is appropriate to achieve those goals.

In general, because the Section 403 guidance was developed for a different purpose and audience, OSWER does not recommend that it be used as a reference in setting PRGs and MCSs or in determining whether action at a particular site is warranted. (To put it another way, it generally should not be treated as a "to be considered" document or "TBC" under CERCLA.) The section 403 guidance is meant to provide generic levels that can be used at thousands of widely varying sites across the nation. The detailed study that goes on at CERCLA or RCRA sites will allow levels to be developed that are more narrowly tailored to the individual site. Nothing in the section 403 guidance discourages setting more site-specific levels for certain situations; in fact, it specifically identifies factors such as bioavailability that may significantly affect the evaluation of risk at some sites.

The IEUBK model. The Agency is further studying both the IEUBK model and analyses of epidemiologic studies in order to better develop the technical basis for rulemaking under TSCA Section 403. The Agency intends to promulgate regulations under Section 403 setting health-based standards for lead in soil and dust. OSWER intends to issue a final soil lead directive once the TSCA Section 403 regulations are finalized. For additional information on TSCA Section 403 developments, call (202) 260-1866.

However, the Agency believes that risk managers (risk assessors, on-scene coordinators, remedial project managers, and other decision-makers at Superfund and RCRA sites) are currently in need of the best guidance available today. The Agency believes that the IEUBK model is the best available tool currently available for assessing blood lead levels in children. Furthermore, use of the IEUBK provides allows the risk manager to consider site-specific information that can be very important in evaluating remediation options. Therefore, using the latest developments in the IEUBK model and the collective experience of the Superfund, RCRA Corrective Action, and TSCA Section 403 programs, the Agency is offering this guidance and is recommending a residential screening level for Superfund and RCRA sites of 400 ppm.

BACKGROUND

Early OSWER guidance (1989-1991). Four guidance documents on the soil lead cleanup were issued by OSWER during the period of 1989 to 1991:

1. September 1989, OSWER Directive #9355.4-02. This guidance recommended a soil lead cleanup level of 500 - 1000 ppm for protection of human health at residential CERCLA sites.

2. May 9, 1990. RCRA Corrective Action program guidance on soil lead cleanup. This guidance described three alternative methods for setting "cleanup levels" (not action levels) for lead in soil at RCRA facilities. One approach was to use levels derived from preliminary results of IEUBK model runs. The other two approaches were to use the range of 500 to 100 provided in the 1989 directive on CERCLA sites, or to use "background" levels at the facility in question.

3. June 1990, OSWER Directive #9355.4-02A. Supplement to Interim Guidance on Establishing Soil Land Cleanup Levels at Superfund Sites. This memorandum reiterated that the September 1989 directive was guidance and should not be interpreted as regulation.

4. August 29, 1991. This supplemental guidance discussed EPA's efforts to develop a new directive that would accomplish two objectives: (1) account for the contribution from multiple media to total lead exposure; and, (2) provide a stronger scientific basis for determining a soil lead cleanup level at a specific site.

Development of the IEUBK Model for OSWER use. During the 1989-91 time period, use of EPA IEUBK model was identified as the best available approach for accomplishing the objectives outlined in the August 1991 guidance. The model integrates exposure from lead in air, water, soil, dust, diet, and paint with pharmacokinetic modeling to predict blood lead levels in children (i.e., Children 6 to 84 months old), a particularly sensitive population.

In the spring of 1991, OSWER organized the Lead Technical Review Workgroup to assist Regional risk assessors and site managers in both using the model and making data collection decisions at CERCLA and RCRA sites. The workgroup was composed of scientists and risk assessors from the Regions and Headquarters, including the Office of Research and Development (ORD), and the Office of Pollution Prevention and Toxic Substances (OPPTS).

In November 1991, the EPA Science Advisory Board (SAB) reviewed the scientific merits of using the IEUBK model for assessing total lead exposure and developing soil lead cleanup levels at CERCLA and RCRA sites. In general, the SAB found the model to be an important advance in assessing potential health risks from environmental contaminants. However, the SAB also recommended additional guidance on the proper use of the model.

In response to SAB concern over the potential for incorrect use of the model and selection of inappropriate input values both for default and site-specific applications, OSWER developed a comprehensive "Guidance Manual for the Integrated Exposure Uptake Biokinetic Model for Lead in Children" (referred to in this interim directive as the "Guidance Manual"). This Guidance Manual assists the user in providing inputs to the model to estimate risks from exposures to lead. It discusses the use of model default values or alternative values, and the application of the model to characterize site risks. Use of the Guidance Manual should facilitate consistent use of the IEUBK model and allow the risk assessor to obtain valid and reliable predictions of lead exposure. The Lead Technical Review Workgroup has been collecting data to further validate the model and to update the Guidance Manual as needed.

Relationship to RCRA Corrective Action "Action" Levels. The approach for calculating a screening level for lead (including exposure assumptions), set forth in this Revised Interim Soil Lead Directive, supersedes the guidance provided for calculating "action" levels set forth in Appendix D of the proposed Subpart S Corrective Action rule. In the July 27, 1990 RCRA proposal (55 *Federal Register* 30798), EPA introduced the concept of "action levels" as trigger levels for further study and subsequent remediation at RCRA facilities. In this respect, the current directive's "screening levels" are analogous to the proposed rule's "action levels." In the proposal, where data were available, action levels were developed for three pathways of human exposure to contaminants: soil ingestion, water ingestion and inhalation of contaminated air. Exposure assumptions used in the calculations were set out in Appendix D of the proposal. For the soil pathway, action levels were calculated two different ways depending on whether the contaminant in the soil was a carcinogen or systemic toxicant. Although lead was listed in Appendix A of the preamble to the rule as a class B2 carcinogen, no action level had been calculated because neither a carcinogenic slope factor (SF) nor a reference dose (RfD) had been developed by the Agency. Although the guidance in Appendix D of the proposed Corrective Action rule remains in effect with respect to other hazardous constituents, this directive now allows for the development of the lead screening ("action") level using the IEUBK model.

Recent developments (1992-Present). Following discussions among senior Regional and OSWER management, the OSWER Soil Lead Directive Workgroup (composed of Headquarters, Regional and other Federal agency representatives) recommended in the spring of 1992 that a "two step" decision framework be developed for establishing cleanup levels at sites with lead-contaminated soils. This framework would identify a single level of lead in soils that could be used as either the PRG for CERCLA site cleanups or the action level for RCRA Corrective Action sites, but would allow site managers to establish site-specific cleanup levels (where appropriate) based on site-specific circumstances. The IEUBK model would be an integral part of this framework. OSWER then developed a draft of this directive which it circulated for review on June 4, 1992. The draft set 500 ppm as a PRG and an action level for RCRA facilities in residential settings.

Following development of this draft, OSWER held a meeting on July 31, 1992 to solicit a broad range of views and expertise. A wide range of interests, including environmental groups, citizens and representatives from the lead industry attended. This meeting encouraged OSWER to think more broadly about how the directive would affect urban areas, how lead paint and dust contribute to overall risk, and blood lead data could be used to assess risk. In subsequent meetings with the Agency for Toxic Substances and Disease Registry (ATSDR) and Centers for Disease Control (CDC), options were discussed on how to use blood lead data and the need to evaluate the contribution of paint. In addition, during these meetings, a "decision tree" approach was suggested that proposed different threshold levels (primary and secondary) for screening decisions, action decisions and land use patterns.

Findings from the three cities (Baltimore, Boston, and Cincinnati) of the Urban Soil Lead Abatement Demonstration Project (peer review scheduled for completion in late 1994) indicate that dust and paint are major contributors to elevated blood lead levels in children. Furthermore, preliminary findings suggest that any strategy to reduce overall lead risk at a site needs to consider not only soil, but these other sources and their potential exposure pathways. (For further information on this demonstration project, contact Dr. Rob Elias, USEPA/ORD, Environmental Criteria And Assessment Office (ECAO), RTP, (919) 541-4167.)

Finally, in its efforts to develop this interim directive, the OSWER Soil Lead Workgroup has met with other EPA workgroups including the TSCA Section 403, Large Area Land Sites, and Urban Lead workgroups, as well as other Federal agencies including the Agency for Toxic Substances and Disease Registry, the Centers for Disease Control, and Department of Housing and Urban Development.

Derivation of Lead Screening Levels. Development of the residential screening level in this interim directive required two important OSWER decisions. 1) OSWER determined that it would seek to achieve a specific level of protectiveness in site cleanups; generally, OSWER will attempt to limit exposure to soil lead levels such that a typical (or hypothetical) child or group of similarly exposed children would have an estimated risk of no more than 5% exceeding the 10 μg lead/dl blood lead level. This 10 μg/dl blood lead level is based upon analyses conducted by the Centers for Disease Control and EPA that associate blood lead levels of 10 μg/dl and higher with health effects in children; however, this blood lead level is below a level that would trigger medical intervention. 2) In developing the residential screening level, OSWER has decided to apply the EPA's IEUBK model on a site-specific basis. This model has been designed specifically to evaluate exposures for children in a residential setting. Current research indicates that young children are particularly sensitive to the effects of lead and require specific attention in the development of a soil screening level for lead. A screening level that is protective for young children is expected to be protective for older population subgroups.

In general, the model generates a probability distribution of blood lead levels for a typical child, or group of children, exposed to a particular soil lead concentration and concurrent lead exposures from other sources. The spread of the distribution reflects the observed variability of blood lead levels in several communities. This variability arises from several sources including behavioral and cultural factors.

The identification of lead exposures from other sources (due to air, water, diet, paint, etc.) is an essential part of characterizing the appropriate blood lead distribution for a specific neighborhood or site. For the purpose of deriving a residential screening level, the background lead exposure inputs to the IEUBK model were determined using national averages, where suitable, or typical values. Thus, the estimated screening level of 400 ppm is associated with an expected "typical" response to these exposures, and should not be taken to indicate that a certain level of risk (e.g., exactly 5% of children exceeding 10 μg/dl blood) will be observed in specific community, e.g., in a blood lead survey.

Because a child's exposure to lead involves a complex array of variables, because there is population sampling variability, and because there is variability in environmental lead measurements and background levels of lead in food and drinking water, results from the model may differ from results of blood lead screening of children in a community. Extensive field validation is in progress. The model will be evaluated further once these efforts are completed.

OBJECTIVE

With this interim directive, OSWER recommends using 400 ppm soil lead (based on application of the IEUBK model) as a screening level for lead in soil for residential scenarios at CERCLA sites and at RCRA Corrective Action sites. Residential areas with soil lead below 400 ppm generally require no further action. However, in some special situations, further study is warranted below the screening level. For example, agricultural areas, wetlands, areas with ecological risk, and areas of higher than expected human exposure are all situations that could require further study. For further guidance on ecological risks, Superfund risk managers are encouraged to consult their Regional Biological Technical Assistance Groups (BTAGs; see Appendix D).

Generally, the ground water pathway will not pose a significant risk since many lead compounds are generally not highly mobile. However, there are situations where, because of the form of lead, hydrogeology, or the presence of other contaminants at the site, lead may pose a threat to the ground water. In these situations, additional analysis is warranted, Superfund Regional Toxics Integration Coordinators (RTICs; seeAppendix B) or RCRA hydrogeologists should be consulted.

While recognizing that urban lead is a significant problem, this interim directive is not designed to be applied in addressing the potential threat of lead in urban areas other than at CERCLA or RCRA Corrective Action sites. Guidance and regulations to be developed under TSCA Section 403 will provide an appropriate tool for addressing urban sites of potential concern.

Generally, where the screening level is exceeded, OSWER recommends using the IEUBK model during the Remedial Investigation or the RCRA Facility Investigation for evaluating potential risks to humans from environmental exposures to lead under residential scenarios. Site-specific data need to be collected to determine PRGs or MCSs. At a minimum, this may involve collecting soil and dust samples in appropriate areas of the site. Further guidance on data collection or modification of the non-residential equation can be obtained by contacting the RTICs or RCRA Regional risk assesors, who in turn may consult the Lead Technical Review Workgroup.

The type of site-specific data that should be collected will obviously depend on a number of factors, including the proximity of residences to the contaminated soil, the presence of site access controls, and other factors that would influence the probability of actual human exposure to the soils. At a minimum, when residences are at or near the site, it is expected that using the model will generally involve taking soil and dust samples from appropriate areas of the site. In many cases, it may not be necessary to gather certain types of data for input into the model. For example, when there are no residences nearby, or where there is otherwise no exposure or very limited exposure to lead contamination, it may not be necessary to collect site-specific data (e.g., dust, water, paint, blood-lead, etc.)

In developing a PRG for CERCLA sites or a MCS for RCRA facilities, EPA recommends that a soil lead concentration be determined so that a typical child or group of children exposed to lead at this level would have an estimated risk of no more than 5% of exceeding a blood lead of 10 μg/dl. In applying the IEUBK model for this purpose, appropriate site-specific data on model input parameters, including background exposures to lead, would be identified.

When the PRG or MCS is exceeded, remedial action is generally recommended. Such action does not, however, necessarily involve excavating soil. A range of possible actions may be considered, as discussed in greater detail under the Implementation section of this directive: Issues for Both Programs.

IMPLEMENTATION
Superfund

This interim directive applies to all future CERCLA Remedial Investigation/Feasibility Study (RI/FS) work; this interim directive should generally not be applied at sites for which risk assessments have been completed. For removal sites, this interim directive recommends that decisions regarding removal actions be considered first by the Regional Decision Team (RDT). The RDT will then refer sites to the removal program for early action, as appropriate.

The approach in this interim directive helps meet the goals set by the Superfund Accelerated Cleanup Model (SACM) for streamlining remedial decision-making. (This streamlined approach is described in Appendix A, Suggested Decision Logic for CERCLA and RCRA Corrective Action.) This interim directive also recognizes that other methods (e.g., slope studies and others) for evaluating risks at lead sites may also be appropriate and may be used in lieu of, or in conjunction with, the IEUBK model. If an alternate approach to lead risk assessment is to be applied, an EPA scientific review should be obtained. For example, expert statisticians would need to review slope factor calculations for statistical biases before their use could be supported. Recognizing that all assessment methods involve some uncertainties, the Agency, at this time, believes the IEUBK model is the most appropriate and widely applicable tool for Superfund and RCRA sites. Alternatively, EPA may require setting cleanup levels below the screening level if site-specific circumstances warrant (e.g., ecological risk). For further information on the use of the IEUBK model at CERCLA sites, contact the Regional Toxics Integration Coordinators identified in Appendix B.

RCRA Corrective Action

It is expected that the RCRA corrective action program will generally follow an approach similar to CERCLA's (as described above) in using the IEUBK model. In the case of RCRA facilities at which lead contaminated soils are of concern, collection and evaluation of data for the purpose of using the model will be primarily the responsibility of the owner/operator.

Issues for Both Programs

Cleanup of soils vs. other lead sources: OSWER's approach to assessing and managing risks from lead is intended to address the multi-media/multi-source nature of environmental lead exposures because it is expected that people at or near CERCLA and RCRA Corrective Action sites will experience lead exposures from sources in addition to contaminated soil. In some instances, these other exposures may be large (e.g., where there are children living in houses with high levels of lead dust form deteriorated paint). The presence of various sources of lead exposure may be very important in both the development of site-specific risk assessments and in the consideration of alternative risk management options.

From an assessment perspective, estimating blood lead levels, that might result from exposures at a site, depends on appropriately integrating exposures from all relevant media. Specifically, it is important to consider direct soil exposures and indoor dust exposures (which can include contributions from both soil and lead-based paint) on a site-specific basis, as well as any contributions from drinking water or other local sources of lead exposure. In using the IEUBK model to estimate blood lead levels, it is important to note that the risk attributable to soil lead exposures is dependent upon the existing level of exposures from other sources. That is, the amount by which the total risk would be lowered if all exposures to lead in soil were removed is not a constant, but varies with the level of existing non-soil exposures. This is because the model derives "distribution" (rather than a simple point estimate) as an output whose shape and size is quite dependent on the predicted variability of exposures from each lead source. As a result, other factors being equal, the risks attributable to soil will generally be higher in the presence of elevated lead exposures from other sources. Therefore, in applying the IEUBK model, the risk attributable to soil lead can be predicted as the difference between the risk estimated when all sources of lead exposure are assessed, and the risk estimated considering only non-soil related exposures. This concept is especially important when evaluating different options for risk reduction at a given site.

From a risk management perspective, achieving a safe environment for populations at CERCLA and RCRA Corrective Action sites may require attention to multiple sources of lead, not all of which may be related to contamination from the source that was the initial concern at the site. Generally, the goal of the Agency, while acting within the constraints of CERCLA and RCRA legal authorities, is to reduce, to the maximum extent feasible, the risk of having significantly elevated blood lead levels. On a site-specific basis this can include remediation approaches that would lead to reduction of exposure from other sources, such as lead-based paint, in conjunction with appropriate soil remediation. Following from the risk assessment discussion in the previous paragraphs, exposures from lead in soils may have a lesser impact in producing high blood lead level if existing exposures from lead in soils may have a lesser impact in producing high blood lead levels if existing exposures from lead-based paint are reduced.

Abatement vs. Intervention: Remedial measures can be divided into those that remove the source of contamination (abatement) and those that leave the contamination in place but block the exposure pathway (intervention). These combinations of measures might include but not be limited to:

Abatement - Soil removal or interior and exterior lead paint abatement.

Intervention - Institutional controls, education/public outreach, gardening restrictions, indoor cleaning and dust removal, or additional cover.

Generally, the most appropriate CERCLA or RCRA response action or combination of actions will be based, in part, on the estimated level of threat posed at a given site. However, as mentioned earlier, key decision criteria also include the overall protectiveness of response options, attainment of Applicable or Relevant and Appropriate Requirements (for CERCLA), a preference for permanent remedies, implementability, cost-effectiveness, and public acceptance. Intervention measures may be more appropriate than abatement (e.g., soil excavation) at many sites, especially in areas where soil lead levels fall at or near the site-specific PRG or MCS.

Addressing exposure from other sources of lead may reduce risk to a greater extent and yet be less expensive than directly remediating soil. In some cases, cleaning up the soil to low levels may, by itself, provide limited risk reduction because other significant lead sources are present (e.g., contaminated drinking water or lead-based paint in residential housing). If it is possible to address the other sources, the most cost-effective approach may be to remediate the other sources as well as, or (if exposures to lead in soil are relatively low) instead of full soil lead abatement.

Lead-based paint can be a significant source of lead exposure and needs to be considered when determining the most appropriate response action. Interior paint can contribute to elevated indoor dust lead levels. In addition, exterior paint can be a significant source of recontamination of soil. Appendix A-3 of this document contains more information on how to evaluate and address the contribution of paint.

Certain legal considerations arise in considering remediation of sources other than soil. In particular, interior exposures from interior paint generally are not within the jurisdiction of RCRA or CERCLA. In addition, where other sources are addressed, issues may arise regarding the recoverability of costs expended by the Agency, or the possibility of claims being asserted against the Fund where other parties are ordered to do the work.

As discussed above, in considering whether to address sources other than soil, it is necessary to consider the risk that would remain from the lead in the soil. In some cases, after risks from other sources have been addressed, unrestricted exposure to soil could be allowed while still being protective (e.g., where the IEUBK model result was heavily affected by the other sources). In other cases, soil risks may still be high enough to require abatement, containment or institutional controls to prevent high levels of exposure. In such cases, before a conclusion is made that the overall remedy will be protective, institutional controls should be carefully studied to make sure that they will be implementable, effective in both the long-term and short-term, and likely to achieve community acceptance.

A potentially useful approach that can be considered in conjunction with other, more active measures in reducing blood lead levels is to develop and promote public education and awareness programs that focus on the causes and prevention of lead poisoning in children. EPA's Office of Pollution Prevention and Toxics (OPPT) provides information on abatement of lead-based paint by the homeowner as well as inexpensive preventive measures the public can take to reduce their exposure to lead. Additional research to evaluate the effectiveness of educational efforts in reducing lead exposures are needed to allow better evaluation of the usefulness of this option. Further, OPPT is assessing the effectiveness of various lead paint abatement options emphasizing low-cost methods. For additional information, contact the National Lead Information Center at 1-800-424-LEAD.

Mining-related sites: Both risk assessors and site managers should be aware that there are a number of factors that affect the relationship between soil lead concentrations and blood lead levels. These factors include the variability in soil lead contribution to house dust levels, or differences in the bioavailability of lead. See discussion in next section, Use of blood lead data, for assessing differences between measured and predicted blood lead levels.

Thus, for mining-related sites without significant past smelting/mill activity, this interim directive encourages further research for characterizing the potential impact of particle size and speciation on soil bioavailability.

Site managers and risk assessors are cautioned that most areas impacted by mining activities are also associated with present or historical smelting or milling operations. Generalizations regarding distinct differences between mining and smelting or milling sites should be avoided until adequate site history and characterization are complete.

Use of blood lead data: In conducting Remedial Investigations (RIs) for CERCLA or RCRA Facility Investigations (RFIs) for RCRA Corrective Action, the interim directive recommends evaluating available blood lead data. In some cases, it may be appropriate to collect new or additional blood lead samples. In general, data from well-conducted blood lead studies of children on or near a site can provide useful information to both the risk assessor and site manager. However, the design and conduct of such studies, as well as the interpretation of results, are often difficult because of confounding factors such as a small population sample size. Therefore, any available blood lead data should be carefully evaluated by EPA Regional risk assessors to determine their usefulness. The Guidance Manual discusses how to evaluate observed blood lead survey data and blood lead data predicted by the IEUBK model.

The Guidance Manual recommends that blood lead data not be used alone either to assess risk from lead exposure or to develop soil lead cleanup levels. During its review of the IEUBK model, the SAB supported this position by asserting that site residents may temporarily modify their behavior (e.g., wash their children's hands more frequently) whenever public attention is drawn to a site. In such cases, this behavior could mask the true magnitude of potential risk at a site and lead to only temporary reductions in the blood lead levels of children. Thus, blood lead levels below 10 μg/dl are not necessarily evidence that a potential for significant lead exposure does not exist, or that such potential could not occur in the future.

Non-residential (adult) screening level. EPA also believes there is a strong need to develop a non-residential (adult) screening level. The IEUBK model is, however, not appropriate for calculating this screening level since it is designed specifically for evaluating lead exposures in children. At this time, EPA is considering a few options for developing this screening level. Several adult models have recently become available. Developing a screening level by using any of them is likely to require significant additional work by the Agency. This work might include testing, validation, and selection of one of the existing models or development of its own model, both of which would require a considerable amount of time. Consequently this would probably be a long-term option. A short-term option would be to develop a screening level based on a simple approach that approximates the more complicated biokinetics in humans. This can serve in the interim while more sophisticated adult lead exposure assessment tools can be identified or developed.

NOTICE: Users of this directive should bear in mind that the recommendations in this document are intended solely as guidance, and that EPA risk managers may act at variance with any of these recommendations where site-specific conditions warrant, as has been noted above. These recommendations are not intended, and cannot be relied upon, to create any rights, substantive or procedural, enforceable by any party in litigation with the United States, and may change at any time without public notice.

Because this document and the related Guidance Manual are not legally binding either upon EPA or other parties, Agency personnel should keep in mind if they are questioned or challenged in comments on a proposed remedial plan, such comments must be considered and a substantive explanation must be provided for whatever approach is ultimately selected. For example, while the IEUBK model is recommended here, its use is not a regulatory requirement and comments on the model or its use should be fully considered.

APPENDICES

A Suggested Decision Logic for CERCLA and RCRA Corrective Action

A-1 Suggested Decision Logic for Residential Scenarios for CERCLA and RCRA Corrective Action

A-2 Suggested Decision Logic for Lead-based Paint for CERCLA and RCRA Corrective Action

B Regional Toxics Integration Coordinators (RTICS)

C Relationship between the OSWER Soil Lead Directive and TSCA Section 403 Guidance

D Biological Technical Assistance Group Coordinators (BTAGS)

Appendix A-1

Suggested Decision Logic for Residential Scenarios for CERCLA and RCRA Corrective Action

Step 1: Determine soil lead concentration at the site.

If soil lead is less than 400 ppm:
STOP, no further action is required, UNLESS special circumstances (such as the presence of wetlands, other areas of ecological risk, agricultural areas, shallow aquifers, or other areas of potentially high exposure) warrant further study.

If soil lead is greater than 400 ppm:
PROCEED to Step 2, UNLESS 400 ppm is selected as a cleanup goal based on consideration of all relevant risk management factors.

Step 2: Evaluate probable land use and develop exposure scenarios.

Step 3: Collect appropriate site-specific data based on selected scenarios.

For example, sampling data may include:

- Soil and dust (at a minimum), paint, water, and air,
- For unique site situations, data on speciation and particle size, and behavioral activities may be required.

Available blood lead data:

- If blood lead data are available, consult the Guidance Manual and Regional Risk Assessor.
- If blood lead data are not available, Regional Risk Assessors and site managers should consider the appropriateness of consulting a blood lead study to supplement available data.

Step 4: Run the IEUBK model with site-specific data to estimate risk and evaluate key exposure pathways at the site.

- If blood lead data are available, compare the data to the model results.

Step 5: Where risks are significant, evaluate remedial options.

If lead-based exterior or interior paint is the only major contributor to exposure, no Superfund action or RCRA corrective action is warranted.

If soil is the only major contributor to elevated blood lead, a response to soil contamination is warranted, but paint abatement is not.

If both exterior lead-based paint and soil are major contributors to exposure, consider remediating both sources, using alternative options as described in Appendix A-2.

If indoor dust levels are greater than soil levels, consider evaluating the contribution of interior lead-based paint to the dust levels. If interior lead-based paint is a major contributor, consider remediating indoor paint to achieve a greater overall risk reduction at a lower cost. (See Appendix A-2.)

NOTE: Available authority to remediate lead-based paint under CERCLA and RCRA is extremely limited.)

Step 6: If the IEUBK model predicts elevated blood leads, rerun the model using the site-specific parameters selected to reflect remedial options in Step 5 to determine site-specific PRGs or MCSs for soil.

Appendix A-2

Suggested Decision Logic for Lead-based Paint for CERCLA and RCRA Corrective Action

(If soil lead levels are below screening levels, lead-based paint could be addressed by authorities other than RCRA or CERCLA.)

If soil lead levels are above screening levels:

Step 1: Examine condition of exterior paint and determine its lead content, if any.

- If the paint is deteriorated, assess contribution or potential contribution of paint to elevated soil lead levels through speciation studies, structural equation modeling, or other statistical methods.

Step 2: Evaluate potential for recontamination of soil by exterior paint.

Step 3: Remediate exterior paint only in conjunction with soil.

- Determine appropriate remediation based on risk management factors (e.g., applying the nine criteria), remediating the major contributor first.

Step 4: Examine condition of indoor paint and determine its lead content, if any.

- If indoor dust lead concentration is greater than outdoor soil lead concentration (because of contamination from both interior paint and outdoor soil), remediate indoor dust (e.g., through a removal action, or making HEPA-VACS available to community).

Step 5: Once the risk from indoor paint has been assessed, examine options to abate indoor paint (e.g., PRP, State, local, HUD) and consult TSCA Section 403 program for additional information and/or guidance.

Step 6: While RCRA and CERCLA have very limited authority regarding the cleanup of interior paint, the remedy may take into account the reduction of total risk that may occur if interior paint is addressed by other means. Thus, for example, a Record of Decision (ROD) or Statement of Basis (SB) may recognize that interior lead-based paint is being addressed by other means, and narrow the response accordingly (possibly making this contingent on completion of the interior lead-based paint abatement effort).

Appendix B

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Appendix C

Relationship between the OSWER Soil Lead Directive and TSCA Section 403 Guidance

Since lead exposures occur through all media, a variety of Agency programs address lead under a number of statutes. Lead in soil is addressed under TSCA Section 403, the RCRA Corrective Action program, and CERCLA, each of which differs somewhat in the types of sites that apply and the types of standards that are used. These differences are primarily due to differences in the purposes of the programs and the authority granted by the statutes under which they are developed. Section 403 soil standards will apply only to residential soil and the current TSCA guidance is generic in nature, with the same standards applying on a nationwide basis. Given the wide applicability of Section 403, generic standards are used in the current guidance in order to reduce resource requirements, as compared to site-specific decisions which can involve expensive and time-consuming analyses. Required RCRA and CERCLA activities are determined on a site-specific basis. The agency's recommendations for evaluating RCRA Corrective Action and CERCLA sites are contained in the OSWER Interim Soil Lead Directive.

In all three of these programs, the Agency's approach is to consider soil lead in the context of other lead sources that may be present and contribute to the total risk. For example, TSCA Section 403 specifically requires the Agency to consider the hazards posed by lead-based paint and lead-contaminated interior dust, as well as lead-contaminated soil. Likewise, the OSWER Soil Directive includes evaluation of other lead sources at a site as part of site assessment / investigation procedures. In addition, the primary focus of the three programs is primary prevention -- the prevention of future exposures from the source(s) being remediated.

The fundamental difference between the relatively new TSCA Section 403 program and the RCRA Corrective Action and CERCLA cleanup programs is that, under current guidance the Section 403 program seeks to establish national standards to prioritize responses to lead hazards whereas the other two programs usually develop site-specific cleanup requirements. This is because TSCA Section 403 deals with a potentially huge number of sites, and resources for the investigation needed to accurately identify their risks are typically very limited. Therefore most decisions under Section 403 will be made with little or no regulatory oversight and clear generic guidelines will be more effective. The more established RCRA and CERCLA programs, on the other hand, deal with a much smaller number of sites, at which extensive site characterization will have been performed before cleanup decisions are made. In addition, these programs have well-established funding mechanisms.

Appendix D

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